

**Notice of Allowability****Application No.**

10/676,944

**Applicant(s)**

HIBNER ET AL.

**Examiner**

JEFFREY G. HOEKSTRA

**Art Unit**

3736

**- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 12/18/2007.
2. ☒ The allowed claim(s) is/are 1 and 3-16.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of the:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.  
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.  
**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20080324.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

/Jeffrey G Hoekstra/  
Examiner, Art Unit 3736

**DETAILED ACTION**

***Notice of Amendment***

1. In response to the amendment filed on 12/18/2007, amended claim(s) 11, 9, and 10 is/are acknowledged. The current rejections of the claim(s) 1 and 3-16 is/are *withdrawn*. The following is/are set forth:

**EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Andrew Ulmer on 3/24/2008.

The application has been amended as follows:

**Claim 1 (Part d. in lines 9-12) should read:**

d. means for applying a first vacuum within the distal end of said needle whereby a portion of **a tissue** to be sampled is drawn into said specimen port when said needle is inserted into the tissue to be sampled,

**Claim 6 should read:**

The biopsy instrument of Claim 5 wherein **the lower lumen** communicates with a source of vacuum.

**Claim 8 should read:**

The biopsy instrument of Claim 1 comprising a specimen collection tube, and wherein the ***specimen collection tube*** and the cutter are configured to advance and retract in unison.

**Claim 9 should read:**

A handheld biopsy instrument comprising:

a biopsy needle having a tissue piercing distal tip and a tissue receiving port disposed proximal of the tissue piercing distal tip, wherein the biopsy needle further comprises a first lumen for receiving ***a hollow cutter***, and a second lumen, wherein the second lumen is external to and parallel to the first lumen, wherein the tissue receiving port is in communication with the first lumen;

***the hollow cutter*** having a distal end, wherein the distal end of the cutter is slidably received within the first lumen of the biopsy needle, and wherein the cutter is rotatable and translatable within the first lumen of the biopsy needle for severing tissue received in the tissue receiving port of the biopsy needle;

***an elongated flexible push rod***, wherein at least a portion of the push rod is slidably received with the second lumen of the needle and extends external to and parallel to the cutter, ***and wherein a distal end of the elongated flexible push rod is adapted to push a tissue sample in a proximal direction into the hollow cutter in***

***response to distal pushing on a proximal portion of the elongated flexible push rod; and***

a specimen tube for receiving tissue severed by the hollow cutter.

**Claim 10 (lines 8-11) should read:**

a flexible push rod, wherein a portion of the flexible push rod is adapted to move distally within the needle, and wherein a distal end of the flexible push rod is ***adapted to push*** a tissue sample in a proximal direction into the hollow cutter in response to distal pushing on a proximal portion of the flexible push rod.

***Allowable Subject Matter***

3. Claims 1 and 3-16 are allowed.
4. The following is an examiner's statement of reasons for allowance: the prior art of record does not disclose, teach, and/or fairly suggest a biopsy instrument, comprising *inter alia*: a push rod and/or a means for causing the push rod to turn, which upon a distal push, engages and pushes a captured tissue specimen in a proximal direction.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Response to Arguments***

5. Applicant's arguments, see pages 6-8, filed 12/18/2007, with respect to the allowability of claims 1, 3-8, and 10-16 have been fully considered and are persuasive. The rejection of claims 1 and 3-16 has been withdrawn.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Application/Control Number: 10/676,944

Page 6

Art Unit: 3736

Jeff Hoekstra

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736